

Linden Flowers and Leaves, Licorice Root, Buckthorn Bark, Calendula Petals"; (btl.) "Herbal Tablet Formula KA 13 Prepared for Pure Grade Health Products, Inc. \* \* \* Caution \* \* \* Active Ingredients \* \* \* Directions"; (box) "Compound Herb Tea Formula No. SL 15 Puregrade Health Products, Inc., Quincy 69, Mass. Net Weight: 4 Oz. \* \* \* Active Ingredients: Senna Leaves, Fennel Seed, Buckthorn Bark, Licorice Root, Bladderwrack, Sweet Orange Peel, Matte, Malva Flowers, Cyani Petals, Mexican Saffron, Calendula Petals. \* \* \*"; (bulk bag) "Formula #SL 15 Contents: Senna Leaves, Buckthorn Bark, Bladderwrack, Fennel Seed, Licorice Root, Sweet Orange Peel, Matte. Directions \* \* \* Use: Laxative \* \* \* Caution."

ACCOMPANYING LABELING: Leaflets entitled "Australian Tea Tree Oil" and "Medicinal Teas and tablets."

RESULTS OF INVESTIGATION: The articles were repacked and relabeled by the dealer from bulk stock shipped as described above. The leaflets were printed locally for the dealer.

LICENSED: 1-18-60, Dist. Mass.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the Tea Tree Oil, namely, the leaflet entitled "Australian Tea Tree Oil," contained false and misleading representations that the Tea Tree Oil was an adequate and effective treatment for healing fungus infections; perionychia; empyema; gynaecological conditions; psoriasis; impetigo; pediculosis; tinea; ringworm; athlete's foot; acute nasopharyngitis; catarrh; thrush; stomatitis; tonsillitis; sore throat; mouth ulcers; insect bites; itches; sores; wounds and abrasions; pimples; boils; carbuncles; and pyorrhea; killing typhoid bacillus; curing colitis; coryza; exposed ulcers; halitosis; gingivitis; pruritic acne; and conjunctivitis; and preventing colds; and the leaflets entitled "Medicinal Teas and Tablets" contained false and misleading representations that the Formula No. KA 13 was an adequate and effective treatment for the temporary and palliative relief of the paroxysms of asthma; and that the Formula No. SL 15 was adequate and effective for controlling weight by eliminating body wastes; and 502(f) (2)—the labeling of the Formula No. SL 15 failed to bear adequate warning against prolonged use, or use in those pathological conditions where its use may be dangerous to health.

DISPOSITION: 3-21-60. Default—destruction.

6172. Various drugs. (F.D.C. No. 44202. S. Nos. 72-946/53 P.)

QUANTITY: 2,000 individually cartoned tubes, 10 tablets each, of *Aspi-Quinine*, 8,500 individually cartoned tubes, 30 tablets each, of *Citrovit*, 800 individually cartoned btl., 40 tablets each, of *Ceferbios Metallic Therapy*, 2,000 individually cartoned btl. of *Bitter Tonio Giuliani*, 3,000 individually cartoned btl., 20 tablets each, of *Giuliani Bitter Laxative*, 250 individually cartoned 150-cc. btl. of *Gastro-Zyme*, 80 individually cartoned boxes of *Coffosil*, 80 boxes, 40 tablets each, of *Zimotris Composition*, at New York, N.Y., in possession of Italian Drugs Importing Co.

SHIPPED: The *Gastro-Zyme* was imported sometime prior to January 1957, and the other articles between 6-21-57 and 7-23-59, from Italy.

LABEL IN PART: (Ctn. & tube) "Aspi-Quinine Each Tab. Con.; Aspirin 0.40 Gm.—Quin. Hydrobromide 0.05 Gm. Indications \* \* \* Warning"; "Citrovit \* \* \* Citro-Alkaline Tablets with Vitamin C Gastric Antacid Dosage:"; (ctn. & btl.) "Ceferbios Metallic Therapy With Vit. B<sub>12</sub> and Folic Acid \* \* \* Each

Tablet Contains: Iron Salt of Inositol Hexaphosphoric Acid 0.20 Gm. Copper Salt of Inositol Hexaphosphoric Acid 0.004 Gm. Manganese Salt of Inositol Hexaphosphoric Acid 0.0065 Gm. Cobalt Salt of Inositol Hexaphosphoric Acid 0.00075 Gm. Folic Acid 0.0005 Gm. Vitamin B<sub>12</sub> 2 Mcgm. Aromatized Sugar q.s. \* \* \* Control No. 26159 Lot No. 513"; "Bitter Tonic Giuliani Each 1 cc. contains: Aromatic Ext. Calamus 25 mg. Tinc. Gentian 40 mg. Acqueous Tinc. Boldus 5 mg.—Sodium Acid Carbonate 5 mg.—Glycerine 50 mg.—Distilled Water 250 mg.—Aromatic Excipients 95% Alcohol 100 mg., Sugar 170 mg., Water 33 mg., 2 drops Mint Essence, 2 drops Anise Essence, 2 drops Cinnamon Essence, 625 mg. Alcohol 14% by volume"; "Giuliani Bitter Laxative \* \* \* Each Tablet contains: Extract Rhubarb 20 Mg.—Extract Cascara Sagrada 20 Mg.—Phenolphthalein 60 Mg.—Excipients and Sugar Q. S."; "Gastro-Zyme I.S.M. Oral Each 100 cc. contains: Extract of fresh gastric mucous of swine 15 Gms. Extract of fresh gastric muscle of swine 10 gms. Peptones from alimentary proteins 7 Gms. Combined in a pleasantly flavored vehicle consisting of glycerin, water and flavor. \* \* \* Control No. 378"; "Coffosil \* \* \* Each 100 grams contains: Thymus Nepeta Extract 2 gm. Potassium Sulfo-guaiacolate 2-5 gm. Sodium Glycerophosphate 1 gm. Sodium Formate 3 gm. Glyceric Syrup Solution Q.S. 100 gm. Indications \* \* \* Suggested Dosage \* \* \* Warning \* \* \* Control No. 593105"; and (box) Zimotris Composition: Each tablet contains: Pepsin 1:2500-50 mg. (Equivalent to 300 Units) Trypsin 1:150-25 mg. (Equivalent to 350 Units) Lipase (F.U.) 25 mg.; Amylase 1:50-50 mg. Indications \* \* \* Dosage."

ACCOMPANYING LABELING: Leaflets entitled "Pharmaceutical Products of Exceptional Merit" and "Specialita' Medicinali Di Porvata Efficacia Curativa," "Giuliani Bitter Laxative Tablets," and "Gastro-Zyme I.S.M."

RESULTS OF INVESTIGATION: The leaflets entitled "Pharmaceutical Products of Exceptional Merit" and "Specialita' Medicina Di Porvata Efficacia Curativa" were printed locally for the dealer and used to promote sales of the articles.

LIBELED: 2-1-60, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the articles, namely, the leaflets entitled "Specialita' Medicinali Di Porvata Efficacia Curativa" and "Pharmaceutical Products" contained false and misleading representations that the *Aspi-Quinine* was an adequate and effective treatment for colds, influenza, neuralgia, and rheumatism; that the *Citrovit* was an adequate and effective treatment for conditions of the liver and intestines, would help to eliminate excess uric acid, correct digestive secretions and was an infallible remedy; that the *Cefebrios Metallic Therapy* was an adequate and effective treatment for the nervous system, for the tired feeling, and for all kinds of anemia; and would make one feel stronger in just a few days; that the *Bitter Tonic Giuliani* was an adequate and effective treatment for dizziness, headache, heartburn, constipation, loss of appetite, hyperacidity, nausea, eructations and other intestinal disturbances; that the *Giuliani Bitter Laxative* was an adequate and effective treatment for habitual constipation; that the *Coffosil* was an adequate and effective treatment for bronchial conditions, bronchial catarrh, sore throat, and laryngitis; and that the *Zimotris Composition* was an adequate and effective treatment for constipation, intestinal fermentation, digestive disturbances, and would eliminate gas, boils, skin eruptions, and arteriosclerosis; 502(b)—the *Citrovit* failed to bear a label contain-

ing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e) (2)—the *Citrovit* was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and 502(f)—The labeling of the *Aspi-Quinine* and the *Giuliani Bitter Laxative* failed to bear (1) adequate directions for use and (2) (*Aspi-Quinine*) adequate warnings for the protection of the user and (*Giuliani Bitter Laxative*) a warning statement for phenolphthalein; 502(a)—when shipped and while held for sale, the labeling of the *Gastro-Zyme*, namely, the leaflet entitled "Gastro-Zyme I.S.M.," contained false and misleading representations that the article was an adequate and effective treatment for chronic (atrophic) gastritis; gastric achylia; dyspepsia in anemic convalescent and aged subjects, infants and over-worked people; gastric neuroses; senile gastric hypotonia and hypochylia; and acute and chronic gastric catarrh.

DISPOSITION: 3-1-60. Consent—claimed by Italian Drugs Importing Co., Inc., New York, N.Y., and relabeled.

**6173. Desitin Rectal Ointment.** (F.D.C. No. 44227. S. No. 67-957 P.)

QUANTITY: 60 individually cartoned tubes at Philadelphia, Pa.

SHIPPED: 12-23-59, from Providence, R.I., by Desitin Chemical Co.

LABEL IN PART: (Ctn. and tube) "1½ Ounces Rectal Desitin Ointment Contains: Zinc Oxide, Norwegian Cod Liver Oil, Lanolin, Talcum, Sodium Lauryl Sulfate, Petrolatum qs. Manufactured by Desitin Chemical Company Providence, R.I."

ACCOMPANYING LABELING: Leaflet in carton entitled "Why New Rectal Desitin Ointment is a superior therapy."

LBELED: 2-10-60, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for hemorrhoids (internal and external), anorectal conditions; pruritus ani; fissures; cryptitis; papillitis; proctitis; perianal dermatitis; and wounds resulting from cryptectomy; proctotomy; fissurectomy; and fistulectomy; and 502(f) (2)—the labeling of the article failed to warn that in case of rectal bleeding a physician should be consulted immediately.

DISPOSITION: 3-9-60. Default—destruction.

**6174. Niagara Cyclo-Massage devices.** (F.D.C. No. 43175. S. No. 16-283 P.)

QUANTITY: 1 glide-out sofa, 2 chaise lounges, 6 thermopads, 22 hand units, 7 all-purpose cushions, 2 #100 provincial chairs, 1 #200 queen chair, 3 #300 king chairs, 3 #400 standard chairs, 1 foam rubber mattress, 1 3-way professional table, 2 executive cushions, 22 sets consisting of thermopads and hand units, at Indianapolis, Ind., in possession of Niagara Distributors, Inc., and Kittle's Niagara Dealers, Inc.

SHIPPED: Between January 1956 and 4-28-59, from Adamsville, Pa.

LBELED: 6-22-59, S. Dist. Ind.

CHARGE: 502(f) (1)—while held for sale, the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of Buerger's disease, wrinkles, crow's feet and bagginess under the chin, skin cancer, cerebral palsy in children, nerve interference, flushing out toxic poisons in the bloodstream, arthritis, bursitis, sinus attacks, high blood pressure, constipation, defective eyesight and hearing, paralysis and blindness